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**PATENT**  
**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Atty Docket No.: A01290B  
TMC/lb

In re Application of:  
Lyn Hughes

Serial No.: 10/679,795 : Group Art Unit: 1615

Filed: October 6, 2003 : Examiner: C. Azpuru

For: IMPROVED PROCESS FOR AMMONIA RECOVERY PHARMACEUTICAL  
FORMULATION INCLUDING A REINSTATE AND AN ADVERSE AGENT

Board of Patent Appeals and Interference  
U.S. Patent and Trademark Office  
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Appeal Brief

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GROUP ART UNIT: 1615  
APPEAL NO. \_\_\_\_\_

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF APPEALS AND INTERFERENCES

**APPELLANT'S BRIEF**

Lyn Hughes

Application for Patent Filed October 6, 2003

Serial No. 10/679,785

PHARMACEUTICAL FORMULATION INCLUDING A  
RESINATE AND AN ADVERSIVE AGENT

James G. Vouros  
Attorney for Appellant

C. Azpuru  
Examiner

Enclosed:  
Amended Brief  
Certificate of Mailing

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DN A01290B US

MAR 20 2008

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**In re application of** : Lyn Hughes  
**Application No.** : 10/679,785      **Group No.** : 1615  
**Filed** : 06-October-2003    **Examiner** : C. Azpuru  
**For** : IMPROVED PROCESS FOR AMMONIA RECOVERY  
PHARMACEUTICAL FORMULATION INCLUDING A  
RESINATE AND AN ADVERSIVE AGENT

Honorable Commissioner of Patents and Trademarks  
Alexandria, VA 22313-1450

**BRIEF FOR APPELLANT**

This is an appeal from the final rejection by the Examiner dated October 26, 2007 rejecting claims 1, 4, and 10 and objecting to claims 5-9. Appellants filed a Notice of Appeal pursuant to 37 C.F.R. § 41.31 on January 22, 2008.

An authorization to charge payment of the fee for the filing of the Appeal Brief to Deposit Account 18-1850 is also enclosed.

**REAL PARTY IN INTEREST [37 C.F.R. § 41.37(c)(1)(i)]**

The real party in interest is the Rohm and Haas Company, the assignee of the patent application by virtue of the named inventor's employment agreement and subsequently executed assignment document.

**RELATED APPEALS AND INTERFERENCES [37 C.F.R. § 41.37(c)(1)(ii)]**

There are no related appeals or interferences to this patent application.

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STATUS OF CLAIMS [37 C.F.R. § 41.37(c)(1)(iii)]

The status of the claims is as follows:

Allowed claim	-	3
Claims objected to	-	5-9
Claims canceled	-	2
Claims pending	-	1, 3-10
Claims rejected	-	1, 4, 10
Claims on appeal	-	1, 4-10

STATUS OF AMENDMENTS [37 C.F.R. § 41.37(c)(1)(iv)]

An amendment after final rejection presenting arguments in support of claims 1, 3-10 was filed on December 26, 2007. An advisory action was just mailed on March 17, 2008. Rejections to claims 1, 4, and 10 and objections to claims 5-9 were maintained in the advisory action. The rejection to claim 3 was withdrawn in the advisory action.

SUMMARY OF CLAIMED SUBJECT MATTER [37 C.F.R. § 41.37(c)(1)(v)]

Appellant's invention is directed to a pharmaceutical comprising, in combination, a resinate and an aversive agent wherein said resinate comprises an ion exchange resin and a drug (*see* Specification; page 4, lines 9-11).

The purpose of this invention is to provide a pharmaceutical which will greatly reduce the ability of abusers to abuse various drugs (*see* Specification; page 2, lines 8-9).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL[37 C.F.R. § 41.37(c)(1)(vi)]

The issue is whether appellant's invention as defined in claims 1 and 4-10 should still be rejected and objected to under a provisional obviousness-type nonstatutory double

patenting rejection when that rejection/objection remains the only rejection of record. Claims 1, 4, and 10 are provisionally rejected under nonstatutory double patenting and claims 5-9 are objected to as being dependant on a rejected base claim.

ARGUMENT [37 C.F.R. § 1.192(c)(1)(vii)]

Rejection of claims 1, 4, and 10 under Nonstatutory Double Patenting

A rejection based on nonstatutory double patenting is based on a judicially created doctrine grounded in public policy so as to prevent the unjustified or improper timewise extension of the right to exclude granted by a patent. *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). Under the Manual of Patent Examination and Procedure, Section 804 I. B:

the courts have sanctioned the practice of making applicant aware of the potential double patenting problem if one of the applications became a patent by permitting the examiner to make a "provisional" rejection on the ground of double patenting.

*In re Mott*, 539 F.2d 1291, 190 USPQ 536 (CCPA 1976);

*In re Wetterau*, 356 F.2d 556, 148 USPQ 499 (CCPA 1966).

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications.

In the instant case the only remaining issue of record is a provisional rejection of claims 1, 4, and 10 based upon nonstatutory double patenting over the claims in co-pending application 10/713,926. Claims 5-9 are objected to as dependant on rejected base claims. However, the appellant has overcome all substantive rejections under 35 U.S.C. 102 and 35 U.S.C. 112. As this is the only rejection remaining in the case, under rule 408 I. B., the provisional nonstatutory double patenting rejection should be withdrawn and the case should be allowed. When this case grants, the Examiner may then issue a double patenting rejection in the co-pending case and require a terminal disclaimer before allowing that application to grant. The current application should not

CLAIMS APPENDIX

1. A pharmaceutical comprising, in combination, a resinate and an aversive agent wherein said resinate comprises an ion exchange resin and a drug.
2. (cancelled)
3. The pharmaceutical of claim 1 in which said aversive agent is selected from the group consisting of capsaicin, derivatives of capsaicin, and mixtures thereof.
4. The pharmaceutical of claim 1 in which said drug is a controlled substance.
5. The pharmaceutical of claim 4 in which both said aversive agent and said controlled substance are loaded onto said ion exchange resin.
6. The pharmaceutical of claim 4 in which said aversive agent is loaded onto said ion exchange resin, and said controlled substance is not loaded onto said ion exchange resin.
7. The pharmaceutical of claim 4 in which said controlled substance is loaded onto said ion exchange resin, and said aversive agent is not loaded onto said ion exchange resin.
8. The pharmaceutical of claim 4 in which said controlled substance is loaded onto a first ion exchange resin, and said aversive agent is loaded onto an ion exchange resin different from said first ion exchange resin.

9. The pharmaceutical of claim 1 in a form that is readily ingestible.
10. The pharmaceutical of claim 1 in the form of a tablet or capsule.

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**EVIDENCE APPENDIX**

None

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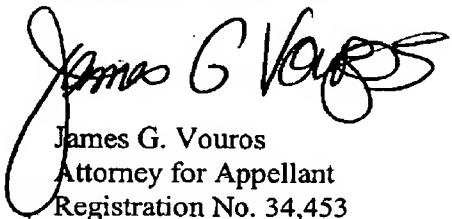
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**RELATED PROCEEDINGS APPENDIX**

None

be prevented from granting based upon a pending application that may or may not ever grant, when no substantive issues exist. Therefore Appellant respectfully requests the Board to reverse the Examiner's rejections and to allow the case. The Commissioner is hereby authorized to charge \$510 for the appeal filing fee, and any additional fee that may be required, or to credit any overpayments to Deposit Account 18-1850.

Respectfully submitted,



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